LAW OFFICES

NIKOLAI, MERSEREAU & DIETZ, P.A.

THOMAS J. NIKOLAI
JAMES T. NIKOLAI
CHARLES G. MERSEREAU
PAUL T. DIETZ

STEVEN E. KAHM
KIMBERLY S. ZILLIG

International Centre
900 Second Avenue South, Suite 820
Minneapolis, Minnesota 55402-3813
Telephone (612) 339-7461
Facsimile (612) 349-6556

PATENTS
TRADE MARKS
COPYRIGHTS
UNFAIR COMPETITION

December 16, 1999

Our Case Docket No. 990326.ORI

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BOX PATENT APPLICATION
The Commissioner of Patents and Trademarks
Washington, D. C. 20231

Sir:

Enclosed herewith for filing is the patent application of inventor(s), DAVID BURTON, for "BIO-MASK" together with the following:

(1) One copy of four (4) sheets of patent drawings;
(2) The Declaration, Power of Attorney and Petition executed by the inventor;
(3) One executed Verified Statement Claiming Small Entity Status – Small Business Concern
(4) An Information Disclosure Statement Under Rule 1.56, Form PTO-1449 and references cited;
(5) An Assignment to COMPUMEDICS HOLDINGS PTY LTD executed by the inventor;
(6) The filing and recording fees are calculated as follows:

Basic filing fee	$ 380.00
Total number of claims in excess of 20, times $9.00	$ 0
Number of independent claims, minus 3, times $39.00	$ 0
Surcharge fee ($130.00) for filing of multiple dependent claim(s) . .	$ 0
Recording fee for assignment	$ 40.00
Total	$ 420.00

A check in the amount of $420.00 is enclosed to cover the filing and recording fees thereon.

The Commissioner is authorized to charge any fees or refund any overpayment under 37 C.F.R. 1.16 and 1.17 which may be required by this paper to Deposit Account No. 08-1265.

Yours very truly,

NIKOLAI, MERSEREAU & DIETZ, P.A.

Steven E. Kahm

Steven E. Kahm

SEK/acl
Encs.

PATENT APPLICATION

ATTORNEY DOCKET NO. 990288.ORI

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re App   :   DAVID BURTON, ET AL.

For   :   RESPIRATORY INDUCTIVE PLETHYSMOGRAPHY BAND
            TRANSDUCER

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27(c)) - SMALL BUSINESS CONCERN

I hereby declare that I am

  ( )   owner of the small business concern identified below:
  (X)   an official of the small business concern empowered to
         act on behalf of the concern identified below:

COMPUMEDICS SLEEP PTY LTD
A Corporation of Australia
1 Marine Parade
Abbotsford, VIC 3067
Australia
A Small Business Concern.

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.12, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention entitled "RESPIRATORY INDUCTIVE PLETHYSMOGRAPHY BAND TRANSDUCER" by inventors, DAVID BURTON and JIAN HONG TAN, described in the specification filed herewith.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having

rights in the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9° if that person made the invention or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e). *NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27).

NAME
ADDRESS
( ) Individual ( ) Small Business ( ) Nonprofit Organization

NAME
ADDRESS
( ) Individual ( ) Small Business ( ) Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this Verified Statement is directed.

NAME OF PERSON SIGNING: David Burton
TITLE OF PERSON IF OTHER THAN OWNER:
ADDRESS OF PERSON SIGNING :62 Broadway, Camberwell, VIC 3124, Australia

SIGNATURE _____   DATE ___1/7/99___ /, 1999.
                                              July 1, 1999

2

1   Attorney Docket Number 990326

2   Bio-Mask

3

4   Inventors: David Burton

5

6   Background of the Invention

7

8   Field of the Invention

9

10   This invention relates to a breathing mask with built in sensors for monitoring

11   patients with sleep apnea, breathing disorders for use during anesthesia or ventilation

12   support.

13

14   Description of the Related Art

15

16   Masks such as shown in patent 5,243,971 for applying a positive pressure to

17   patients with apnea and other breathing disorders have been developed. These masks

18   provide seals for preventing air from escaping from the mask at the junction of the mask

19   and face. Other types of masks for gas delivery to a patient are also in common use.

20   Measuring air flows to a patient has been accomplished by metering sensors in the

21   air supply connected to the mask as in patent 5,503,146 or by belts around the patients

22   chest to measure his breathing as in patent 5,131,399.

1   Some devices such as in patent 5,507,716 provide sensors combined with sleep

2   masks for covering the eyes of a patient. However there is no known example of sensors

3   built into breathing masks for monitoring or studying patients with breathing disorders.

4   Currently if a patient is to be carefully monitored a plurality of electrodes or

5   sensors would have to be individually applied to the patient and wired to recording

6   equipment. The plurality of sensors and tangle of ensuing wires impede the usage of such

7   monitoring equipment. Sensors providing useful information include Electro-

8   encephalogram (EEG), electromyography (EMG), electro-oculogram (EOG), electro-

9   cardiogram (ECG), Pulse Transit Time (PTT), gas flow sensors, temperature sensors,

10   microphones, blood oxygen meters, blood pressure sensors, pulse sensors, patient

11   movement, position, light, activity sensors, mask leakage, mask pressure, eye movement

12   (PVD or Piezo) and other means of gathering data about the patient or his environment.

13   It is very inconvenient for the patient and the health care worker to attach a series

14   of different devices to a patient to monitor a plurality of different parameters

15   simultaneously. Therefore a single device for easily measuring a plurality of parameters

16   is desired.

17

18   Summary of the Invention

19

20   The invention relates to providing sensors in breathing masks to make it easy to

21   monitor a patient. The mask has a soft pliable seal material around its perimeter in

22   contact with the patient's face to form a secure seal therewith. Sensors may be recessed

23   into the soft pliable seal material at the surface for contact with the skin of the user when

1   the mask is applied to the user's face. The wiring for the sensors may be inside the soft

2   pliable seal material insulating the wires from damage during use of the mask. Many

3   sensors can be incorporated into the mask. Sensors may be placed on the perimeter or on

4   other portions of the mask not in contact with the skin. Sensors may also be placed on

5   straps or caps used in conjunction with the masks or on other devices used with the mask.

6   Monitoring of patients with sleep disorders, breathing disorders or for anesthesia

7   is made easier and more convenient for the patient and for the health care provider since

8   all the sensors needed are built into a mask which is easily and quickly placed on the

9   patient with all the wiring to the sensors integral with the mask and accessed by a single

10   plug.

11   The types of sensors on or in the mask and straps or caps connected to the mask

12   include but are not limited to oximetery sensors, patient position sensors, eye movement

13   sensors, leak detection sensors, EEG, EMG, EOG, ECG, PTT, microphones, pulse, blood

14   pressure, oxygen saturation, temperature, movement sensors, position sensors, light

15   sensors, leak detection sensors and gas delivery sensors.

16   Connections to outside sources of gases delivered to the mask are by a gas nozzle

17   hook up on the mask. A connection to electrical power and data output cables are by a

18   plug in to a cable connecting to the mask. Alternatively batteries in the mask and

19   telemetry equipment in the mask can provide power and transmission of the data to a

20   microprocessor or computer. For portability the microprocessor can be attached to the

21   mask or be carried by the patient. Similarly a bottle of gas may be connected to the mask

22   and carried by the patient to allow mobility of the patient while wearing the mask.

1   Unique applications for the bio-mask include the capability to apply anesthesia-

2   depth monitoring while administering anesthesia gas to a subject. The ability to monitor

3   the patient non-invasively with the bio-mask while at the same time administering the

4   anesthesia gas to the patient provides a bio-feedback function for immediate and

5   responsive anesthesia depth of the subject. The bio-mask can be used to determine the

6   subject's sleep state by applying standard sleep staging criteria, such as that of R&K rules

7   and/or the application of diagnostic techniques which analyze a number of EEG signals,

8   such as Bispectral Analysis. The invention is unique in its capability to apply such

9   analysis with the minimal-invasive application of a subject breathing mask.

10   R&K rules refer to "A Manual of Standardized Terminology, Technicques and

11   Scoring System for Sleep Stages of Human Subject" by Rechtschaffen and Anothony

12   Kales, Editors 1968 which is hereby made a part hereof and incorporated herein by

13   reference.

14

15   Objects of the Invention

16

17   It is an object of the invention to monitor a patient.

18   It is an object of the invention to provide data needed to help treat a patient.

19   It is an object of the invention to provide sensors for monitoring a patient in or on

20   a breathing mask or on its associated parts.

21   It is an object of the invention to regulate the flow of gasses to a patient based on

22   the data obtained from monitoring the patient.

1   It is an object of the invention to diagnose the patient based on data obtained from

2   monitoring the patient.

3   It is an object of the invention to easily and quickly apply all the sensors needed

4   for monitoring the patient.

5   Other objects, advantages and novel features of the present invention will become

6   apparent from the following detailed description of the invention when considered in

7   conjunction with the accompanying drawing.

8

9   Brief Description of the Drawings

10

11   Fig. 1 shows a schematic view of the zones for sensors on the inside surface of a soft

12   pliable material on the perimeter of the breathing mask.

13   Fig. 2 shows a view of the sensors and wiring inside the soft pliable material on the

14   perimeter of the breathing mask.

15   Fig. 3 shows a side schematic view of the sensors and the wiring inside of the soft pliable

16   material on the perimeter of the breathing mask.

17   Fig 4 shows a side schematic view of the straps connected to the mask with sensors

18   embedded in the straps and the mask.

19   Fig. 5 shows a schematic view of the sensor zones on the perimeter of the breathing

20   mask.

21   Fig. 6 shows a schematic view of the sensors on the inside surface of a breathing mask.

22   Fig. 7 shows a side schematic view of the mask with sensors on the surface of the mask.

23

1   Description of the Preferred Embodiments

2

3   Fig. 1 shows the inside of mask 10 including the perimeter surface 12 which

4   contacts the patient's face. The perimeter surface 12 has a plurality of zones 20. Each

5   zone 20 having a sensor 25 in a recess 29 for measuring a parameter of the patient to be

6   monitored or other data such as gas leakage. Other sensors 26 are on the mask 10 but not

7   in contact with the patient's skin. These sensors 26 measure patient data or related data

8   such as ambient light, gas pressure in the mask or ambient temperature. The mask 10 has

9   a gas connector 14 for connecting a hose 32 to provide a gas to the mask 10 and a mask

10   interface connector 16 for plugging in a cable 30 for a power supply and for data

11   transmission.

12   In some embodiments of the invention the sensors 25 do not require an outside

13   source of power as the sensors such as heat sensors and light sensors generate current.

14   The mask perimeter surface 12 is preferably made out of a soft pliable material

15   such as silicone rubber for making a good sealing contact with the face of the patient to

16   prevent gas leakage. The material should be soft and pliable enough to follow the

17   contours of the face. The perimeter surface preferably has recesses 29 on the surface for

18   the insertion of sensors 25 so that the sensors can make contact with the patient's skin

19   when the mask is pressed against the patient's face.

20   As seen in Fig. 3 a sensor or electrode 25 attachment to the mask 10 preferably

21   utilizes a rubber compound 28 such as silicon or other food grade type rubber embedded

22   with carbon or other conductive materials for electrical contact of skin to the mask. As

23   shown in Fig. 2 the recesses 29 are large enough to have room to make electrical

1   connections to leads 27, which are buried in the soft pliable material under the perimeter

2   surface 12. The leads 27 are thus protected from damage and electrically insulated.

3   Preferably the sensors 25 will plug into the leads 27 or printed circuits in the recesses 29.

4   The leads 27 are preferably on printed circuits embedded in the mask or fine wires

5   embedded in the mask and connect the sensors 25 to the mask interface connector 16.

6   Fig. 5 shows conductive material 40 on the surface in zones 20, such as carbon

7   embedded silicon, can be used on the surface of the perimeter 12 of mask 10 in separate

8   zones 20 to conduct the electrical surface energy from the patient's face. The conductive

9   material 40 is preferably moisture activated to improve the its electrical conductivity

10   when in contact with the skin. The conductive material 40 may be applied for all

11   electrode 25 contacts in all zones 20. Alternatively electrodes 25 may directly contact the

12   patients face. The electrodes may also be inside of the soft pliable material on the

13   perimeter 12 of the mask 10.

14   Fig. 4 shows a side view of the mask 10 and straps 35 used to keep the mask in

15   place on a patient. The straps 35 have sensors 25 connected to leads 27, which connect

16   the sensors to the mask interface connector 16 and to cable 30 for transmitting data to a

17   computer or other device. The sensors 25 in the straps 35 may be electro-encephalogram

18   EEG sensors for measuring brain waves. The straps 35 may be replaced with a cap

19   having sensors therein. Alternatively a chin strap 37 may be used having sensors 25.

20   Fig. 5 shows an example of the types of sensors 25 used in zones 20 around the

21   perimeter of the mask 10. Physiological signals from a patient's skin potential are

22   detected by sensors in the zones 20 around perimeter 12 of mask 10. Conductive

23   electrode paste 40 may be used to improve the electrical contact between the sensors 25

1   and the surface of the skin. The conductive paste 40 can assist in reducing the impedance

2   between the face and the electrical output from the sensors 25 in zones 20. The

3   conductive paste 40 may also assist in preventing gas leaks.

4   As an example of a mask sensor layout the following sensors and their functions

5   are described. However many other types of sensors and arrangements of the sensors are

6   possible.

7   Zone 50 is an electro-oculogram (EOG) to obtain electrical eye movement

8   reference signals from over the bridge of the nose.

9   Zone 51 is an EOG to detect electrical eye movement signals for the inner left eye

10   and zone 61 is designated for electrical eye movement signals for the inner right eye. Eye

11   movement data is related to stages of sleep such as rapid eye movement REM, which

12   indicates a deep sleep state and dreaming.

13   Zone 52 is designated for an EOG to detect electrical eye movement signals for

14   the outer left eye and zone 62 is designated for electrical eye movement signals for the

15   outer right eye.

16   Zone 53 is designated for electro-myography (EMG) to detect electrical signals

17   from muscle contractions in the upper left chin. Zone 63 is correspondingly for the upper

18   right chin. Zones 54 and 64 are for the lower left and lower right chin respectively. The

19   amplitude of the chin signals is proportional to the relaxation state and subsequent sleep

20   state of the patient.

21   Zone 55 is the EMG for the upper left lip, giving information about sleep stages.

22   It is proportional to the relaxation and sleep states of the patient. Zone 65 is the EMG for

23   the upper right lip.

1   Zone 56 is the EMG for the left nasal inner mask it also provides signals for the

2   lip movements and is proportional to the relaxation and sleep states of the patient.

3   Similarly zone 66 is for the right nasal inner mask EMG.

4   Zones 57 and 67 are for the oral left and oral right outer mask EMG signals which

5   are also proportional to the relaxation and sleep states of the patient.

6   Zone 70 is for pressure sensor ports for airflow determination.

7   Microphone 80 on the mask detects the patients breathing or snoring sounds.

8   Fig. 6 shows an alternate embodiment where two sensors 58 and 68 are used to

9   find the patient's electrocardiogram ECG. This data is also useful for monitoring a

10   patient. The patient's heart functions provide a lot of useful data about the patient's

11   condition. Pulse Transit Time (PTT) is the time it takes ECG pulses to travel from the

12   heart to a sensor such as a sensor placed on the head, on a finger tip, or on the ear. PTT

13   sensors can be in the mask, on sensors connected to the mask, or sensors used in

14   conjunction with the mask. PTT measurements are used to determine patient arousals and

15   qualitative blood pressure variation.

16   Thermal sensor 81 is used on the inside surface of the mask to detect nasal

17   breathing. Thermal sensor 82 is used on the outside surface of the mask to detect oral

18   breathing. The thermal sensitivity of the sensors 81 and 82 on the surface of the mask 10

19   opposite the nose or mouth indicates if the patient is breathing through his nose or mouth.

20   The thermal sensors 81, 82 may alternatively be placed on the inside of the mask 10, on

21   the outside of the mask10, or inside of the material of mask 10 for detecting breathing.

22   The thermal sensors 81, 82 may be a thermistor material, a thermocouple material or any

23   other temperature sensitive material. The thermal sensors 81, 82 may be coatings on the

1   inside of the mask, the outside of the mask or in the mask. The thermal sensors 81, 82

2   detect heat, which is proportional to the amount of breathing.

3   It is important to detect oral breathing for undetected or partially undetected oral

4   breathing effects the integrity of the patient breathing gas breath monitoring and

5   subsequently compromises the idea gas delivery to the patient. It is important to detect

6   mouth breathing to assist in diagnosis of sleep disordered breathing. Further, control of a

7   mask nasal ventilation is effected by mouth breathing.

8   A pressure sensor 84 measures the pressure inside of the mask to indicate if there

9   is positive pressure inside of the mask and how much. A pressure drop may indicate a

10 leak.

11   A surface reflective oximetry sensor 85 on the inside of the mask detects the

12 patients pulse rate and oxygen saturation.

13   A surface blood pressure sensor 90 on the perimeter 12 of the mask10 in contact

14 with the patient can be used to monitor the patients blood pressure.

15   A thermistor 91 on the perimeter 12 of the mask 10 in contact with the patient can

16 be used to monitor the patients temperature.

17   A patient recycled air detection system having a sensor 95 on the inside surface of

18 the mask detects the amount expired air from the patient remaining in the mask 10. High

19 levels of expired gas in the mask indicates the mask is not being flushed out and may lead

20 to problems if not enough fresh gas is introduced.

21   A patient back gas occurrence detector 97 in the mask hose connector 14 detects

22 the amount of expired gas in the mask returning with newly delivered gas.

1   Fig. 7 shows thermal sensors 83 such as thermistors or thermocouples on the

2   inside or outside of the mask adjacent the perimeter 12. These sensors can be attached to

3   a thermally conductive material 92 around the perimeter of the mask 10. Alternatively the

4   thermally conductive material may be on portions of the perimeter. This thermally

5   sensitive material can be on the inside surface of mask 10, the outside surface of mask 10

6   or embedded within the mask material. Detection of a temperature change by thermal

7   sensors 83 or thermal sensors 83 on thermally conductive material 92 correlates with

8   mask leakage around the perimeter. The thermally sensitive material may be a thermally

9   sensitive material in the mask on the inside of the mask, on the outside of the mask or on

10 the perimeter of the mask. The thermally sensitive material may be a thermistor, a

11 thermocouple, or any other thermally sensitive material.

12   Gases leaking from the mask 10 will cause a temperature change associated with

13 the thermally conductive material 92 and sensors 83 and allow a healthcare specialist

14 real-time monitoring of leak status or post monitoring status of mask leakage. In some

15 instances this can be life saving where a patient's gas delivery is critical and in other

16 cases the leakage incidence can assist in the diagnosis of a patient. This assistance may be

17 in the form of alerting a health care specialist that the gas delivery was subject to leakage

18 and this may affect patient treatment and patient diagnostic conditions. In other instances

19 the gas leakage detection can allow the gas delivery system to automatically compensate

20 for the gas leakage.

21   A light sensitive resistor 86 on the outside surface of the mask 10 indicates the

22 ambient lighting conditions of the patient.

1   Position sensors 87 indicate position or activity of the patient. For example these

2   sensors show if the patient is lying down and is motionless. Such a sensor may be a

3   moving ball across switch contacts, or mercury sensor switches.

4   Body movement sensor 88 can be a PVD or piezo material or micro mechanical to

5   detect the patients body movements extent and rate to determine a wake versus rest state.

6   All of the above sensors may send data by telemetry rather than by cable 30.

7   All of the above collected data may be used to monitor a patient for a variety of

8   uses including sleep studies, anesthesia and sleep apnea.

9   The data collected can be converted to a serial data stream to allow a single wire

10   to interface all the sensors. The sensors may provide data to adjust gas delivery to the

11   patient.

12   Gain and filtering adjustments to the signals may be used to condition the signals

13   close to source for optimal noise and signal performance.

14   An electrical bias to sensors such as a patient position sensors, thermal conductive

15   zones, microphones, or light dependent resistor may be applied.

16   A computer may process the data or simply store the data to from the monitoring

17   sensors in the mask or straps attached thereto. The monitoring data may be used to

18   diagnose a patient, provide feedback to machines attached to the patient, increase or

19   decrease air supplies to a patient or perform other functions.

20   An example of EEG data controlling in a bio-feedback application the delivery of

21   gas to a patient may be when a patient has a nasal ventilation device such as a ventilator

22   Continuous Positive Air Pressure (CPAP), Bi-Positive Air Pressure (BIPAP), Variable

23   Positive Air Pressure (VPAP), Sleep Linked Positive Air Pressure (SPAP) and the EEG

1 electrodes provide one of the vital signs of if the patient is asleep. Gas is only applied to

2 the mask when the patient is deemed to be asleep. This function is more sophisticated,

3 sensitive to patient comfort and commercially viable than delay ramp systems used on

4 some ventilation systems.

5   In ventilation devices that use delay ramps the user sets a time of the system

6 allocates a time and ramps up the gas pressure delivery to the patient so that the

7 application of gas does not have as much disturbing affect on the user and adversely

8 effect his ability to sleep.

9   The sensors in the mask 10 are better able to determine when the patient is

10 actually asleep before applying assisted nasal ventilation. Premature application of

11 pressure can prevent the patient from sleeping due to the added discomfort of positive

12 pressure.

13   The mask 10 may be made such that it is a sterile disposable unit for medical use

14 thus lowering costs of treatment by not needing to sterilize masks for new patients and

15 providing a more sterile treatment than reusable masks.

16   Obviously , many modifications and variations of the present invention are

17 possible in light of the above teachings. It is therefore to be understood that, within the

18 scope of the appended claims, the invention may be practiced otherwise than as

19 specifically described.

20   What is claimed is:

21

1

1   1.   A mask with sensors for monitoring a patient during gas delivery comprising:

2   a mask having a perimeter for contacting the face of a patient,

3   at least one sensor on the mask to sense at least one parameter indicating a state of

4   the patient,

5   leads in the mask connected to the at least one sensor for transmission of data,

6   a means for transmitting data from the mask,

7   a hose connector on the mask for attachment of a hose for delivery of gas to the

8   mask.

1

1   2.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   the means for transmitting data from the mask comprises a mask interface

4   connector for connecting the leads in the mask to a cable.

1

1   3.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   comprising,

3   a means for providing power to the mask to operate the sensors.

1

1   4.   A mask with sensors for monitoring a patient during gas delivery as in claim 3

2   wherein,

3   the means for providing power to the mask to operate the sensors comprises a

4   mask interface connector connecting a power source lead to a lead in the mask for

5   transmitting power to a sensor and;

6   the means for transmitting data from the mask comprises a mask interface

7   connector for connecting the leads in the mask to a cable.

1

1   5.   A mask with sensors for monitoring a patient during gas delivery as in claim 3

2   wherein,

3   the means for providing power to the mask to operate the sensors comprises a

4   battery attached to the lead in the mask for transmitting power to a sensor and;

5   the means for transmitting data from the mask comprises a telemetry device.

1

1   6.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   the sensors on the mask are selected from the group consisting of, EEG, EMG,

4   EOG, ECG, PTT, temperature, surface blood pressure, pulse, blood oxygen level, light,

5   breathing rate, breathing volume, gas flow, nasal air flow, oral air flow, position, activity

6   sensors, mask leakage, mask pressure, eye movement, microphones, gas pressure, patient

7   recycled air detection, patient back gas and movement.

1

1   7.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3　　　　　at least one sensor on the perimeter of the mask makes contact with the skin of the

4　　patient for measuring a parameter.

1

1　　8.　　　A mask with sensors for monitoring a patient during gas delivery as in claim 7

2　　wherein,

3　　　　　the perimeter of the mask has a soft pliable material for contacting the face of the

4　　patient.

1

1　　9.　　　A mask with sensors for monitoring a patient during gas delivery as in claim 8

2　　wherein,

3　　　　　the material has at least one recess with a sensor in the recesses for contacting the

4　　skin of the patient.

1

1　　10.　　A mask with sensors for monitoring a patient during gas delivery as in claim 9

2　　wherein,

3　　　　　leads in the pliable material are connected to the at least one sensor for power and

4　　data connections therewith.

1

1　　11.　　A mask with sensors for monitoring a patient during gas delivery as in claim 8

2　　wherein,

3　　　　　a carbon embedded rubber material provides electrical contact between the sensor

4　　in the soft pliable material and the patient's skin.

1

1

1   12.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   the mask has at least one strap attached to the mask to hold the mask in place.

1

1   13.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   the mask has at least one strap attached to the mask to hold the mask in place and

4   the strap has at least one sensor wired to the mask for monitoring the patient.

1

1   14.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   the mask has a cap attached to the mask to hold the mask in place.

1

1   15.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   the mask has a cap with at least one sensor attached to the cap, the sensor leads on

4   the cap connected to the leads in the mask for monitoring the patient.

1

1   16.   A mask with sensors for monitoring a patient during gas delivery as in claim 13

2   wherein,

3   the strap includes a chin strap.

1

1   17.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   at least one sensor in the chin strap for measuring chin EMG

1

1   18.   A mask with sensors for monitoring a patient during gas delivery as in claim 13

2   wherein,

3   the straps include a head strap having a sensor for measuring EEG.

1

1   19.   A mask with sensors for monitoring a patient during gas delivery as in claim 15

2   wherein,

3   the cap includes sensor for measuring EEG.

1

1   20.   A mask with sensors for monitoring a patient during gas delivery as in claim 13

2   wherein,

3   the strap includes an ear strap having an oxygen saturation sensor applied to the

4   ear of the patient.

1

1   21.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   a thermal sensor on a portion of the mask detects changes in temperature on that

4   portion of the mask.

1

1   22.   A mask with sensors for monitoring a patient during gas delivery as in claim 21

2   wherein,

3   the mask has a thermally conductive material to which the thermal sensors are

4   thermally coupled.

1

1   23.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   a thermally sensitive material on the mask proximate the patient's nose detects

4   temperature variations for nasal breathing detection.

1

1   24.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   a thermally sensitive material on the mask proximate the patient's mouth detects

4   temperature variations for oral breathing detection.

1

1   25.   A mask with sensors for monitoring a patient during gas delivery as in claim 1

2   wherein,

3   a thermally sensitive material on the mask proximate mask perimeter detects

4   temperature variations for leak detection.

1

1   26.   A mask with sensors for monitoring a patient during gas delivery as in claim 21

2   wherein,

3   the thermally sensitive material comprises a thermistor.

1

1   27.   A mask with sensors for monitoring a patient during gas delivery as in claim 21

2   wherein,

3   the thermally sensitive material comprises a thermocouple.

1

1   28.   A mask with sensors for monitoring a patient during gas delivery as in claim 21

2   wherein,

3   the thermally sensitive material comprises a coating on the mask.

1

1   29.   A mask with sensors for monitoring a patient during gas delivery as in claim 21

2   wherein,

3   the thermally sensitive material portion of the mask comprises an internal surface·

4   portion of the mask.

1

1   30.   A mask with sensors for monitoring a patient during gas delivery as in claim 21

2   wherein,

3   the thermally sensitive material portion of the mask comprises an external surface

4   portion of the mask.

1

1   31.   A mask with sensors for monitoring a patient during gas delivery as in claim 21

2   wherein,

3   the thermally sensitive material portion of the mask comprises a portion within

4   the mask material.

1

1   Abstract of the Disclosure

2   The invention relates to a breathing mask for use in monitoring a patient. The

3   mask provides sensors built into the mask for ease of application to a patient such that

4   donning the mask places all the required sensors on the patient. The mask has a perimeter

5   with a soft pliable material with sensors therein for contacting the skin of the patient and

6   making an airtight seal. The mask also has sensors on the body of the mask and on the

7   associated straps or caps. Sensors may also be independently applied to the patient and

8   work in conjunction with the sensors on the mask. The sensors can be used for

9   monitoring the patients EMG, EEG, EOG ECG, surface blood pressure, temperature,

10   pulse, blood oxygen the position of the patient, the activity level of the patient, the sounds

11   coming from the patient, and the gas pressure in the mask. In addition the mask may

12   measure the leakage rates of the mask, the gas pressure inside the mask, the gas flow into

13   the mask, the patients breathing rate, the volume of breathing, nasal breathing, oral

14   breathing, and the ambient temperature and light levels. The mask can be used to monitor

15   breathing problems, including sleep apnea or to monitor a patient during administration

16   of anesthesia. The data acquired from the mask sensors and related sensors can be stored

17   or fed into a computer to analyze the patient's condition and provide feedback

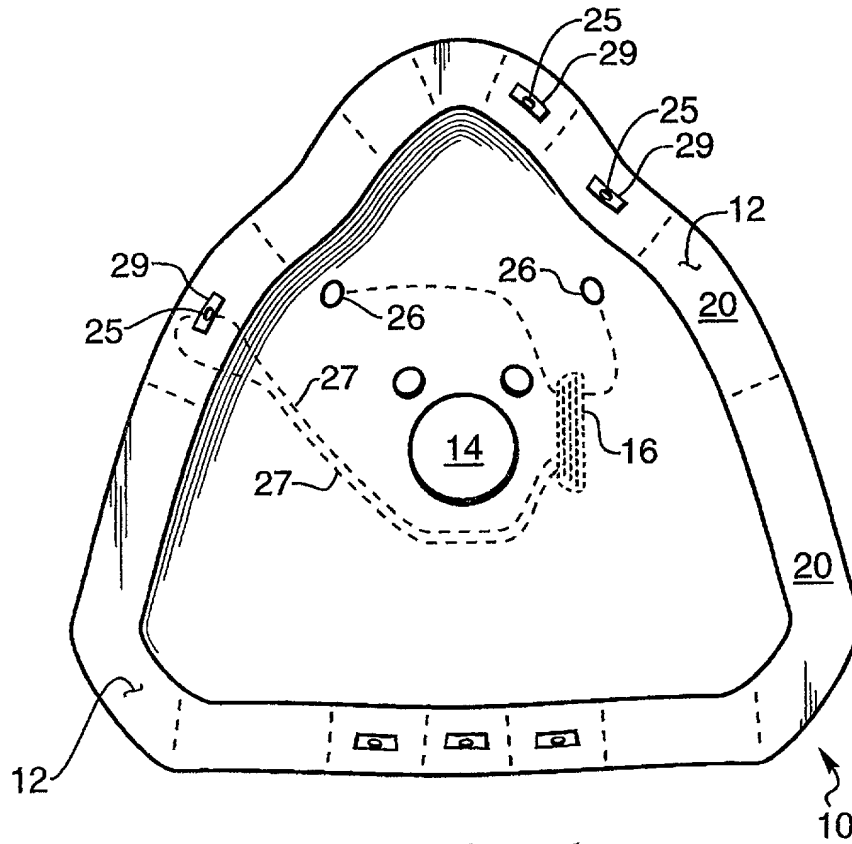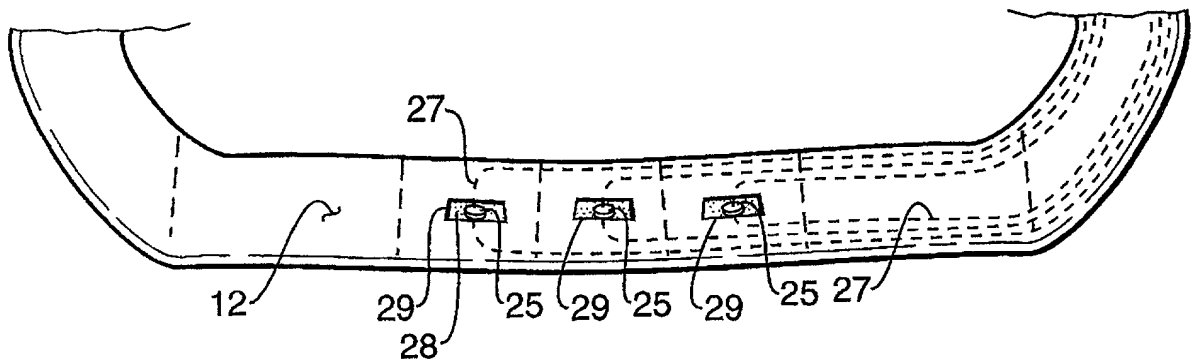18   information for administering gas to the mask.
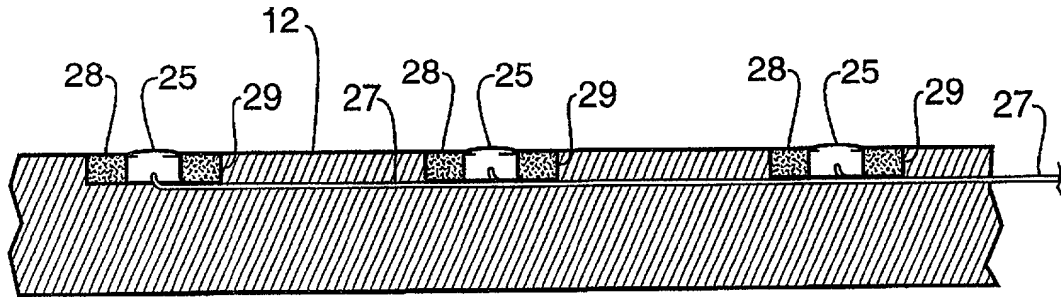
19

1/4

Fig. 1

Fig. 2

28 25   29   12 27 28 25   29   28 25   29   27

Fig. 3

25   27   25   35

25   25

25   25

25

27

35   27   25   12 25

27   25

16 14 32

30

27

27
25

37 10

Fig. 4

Fig. 5

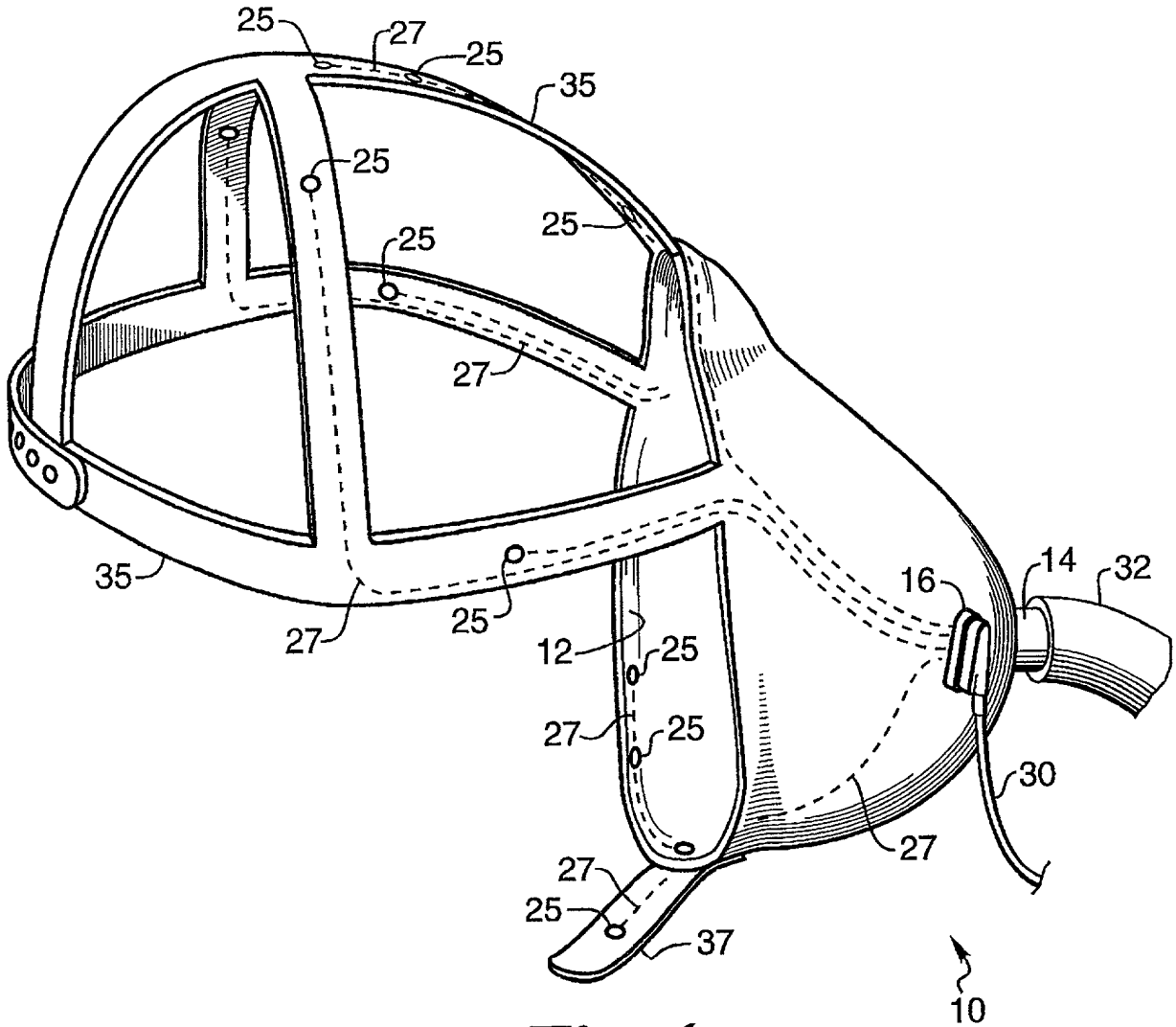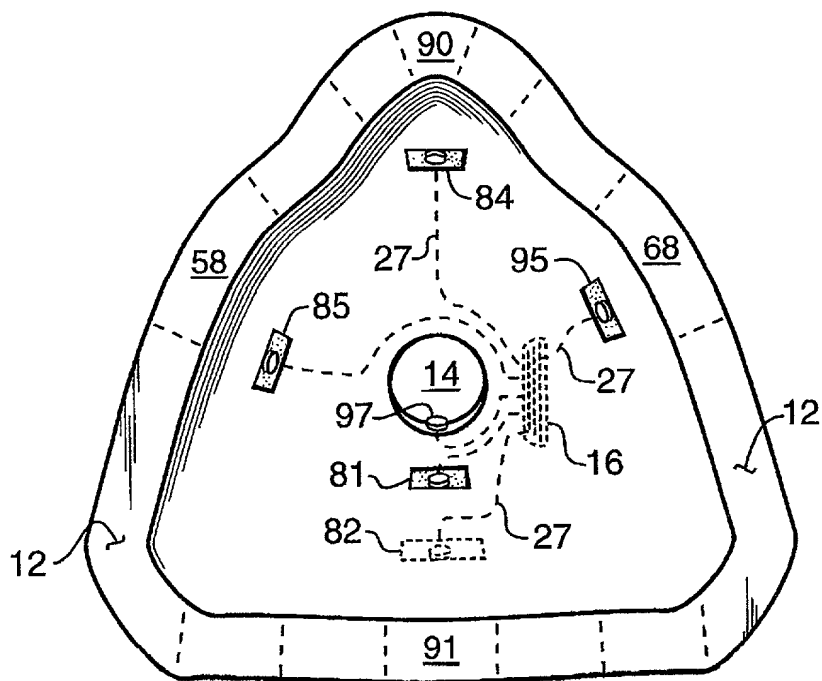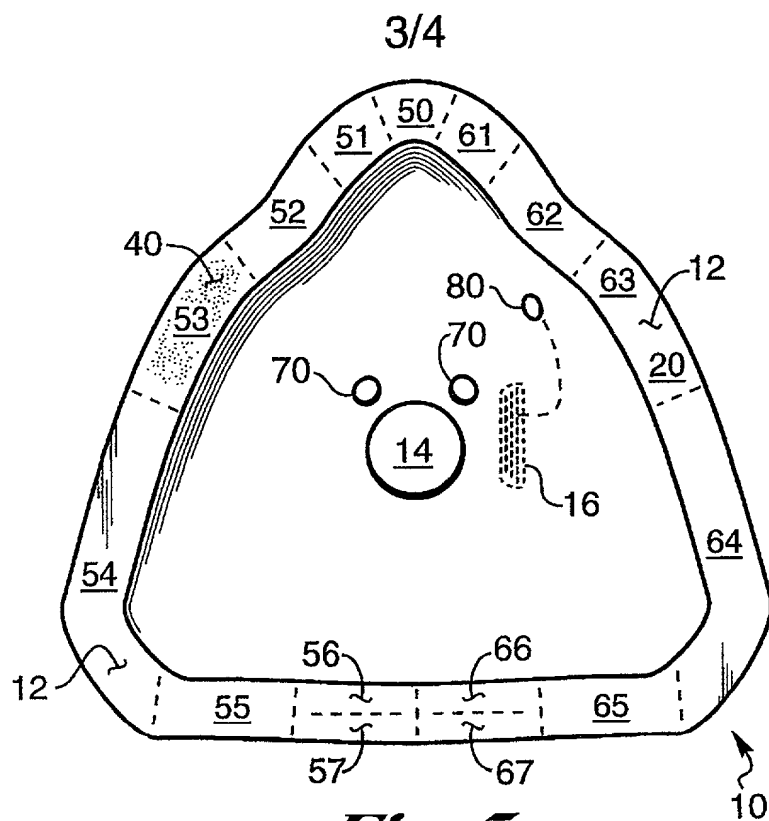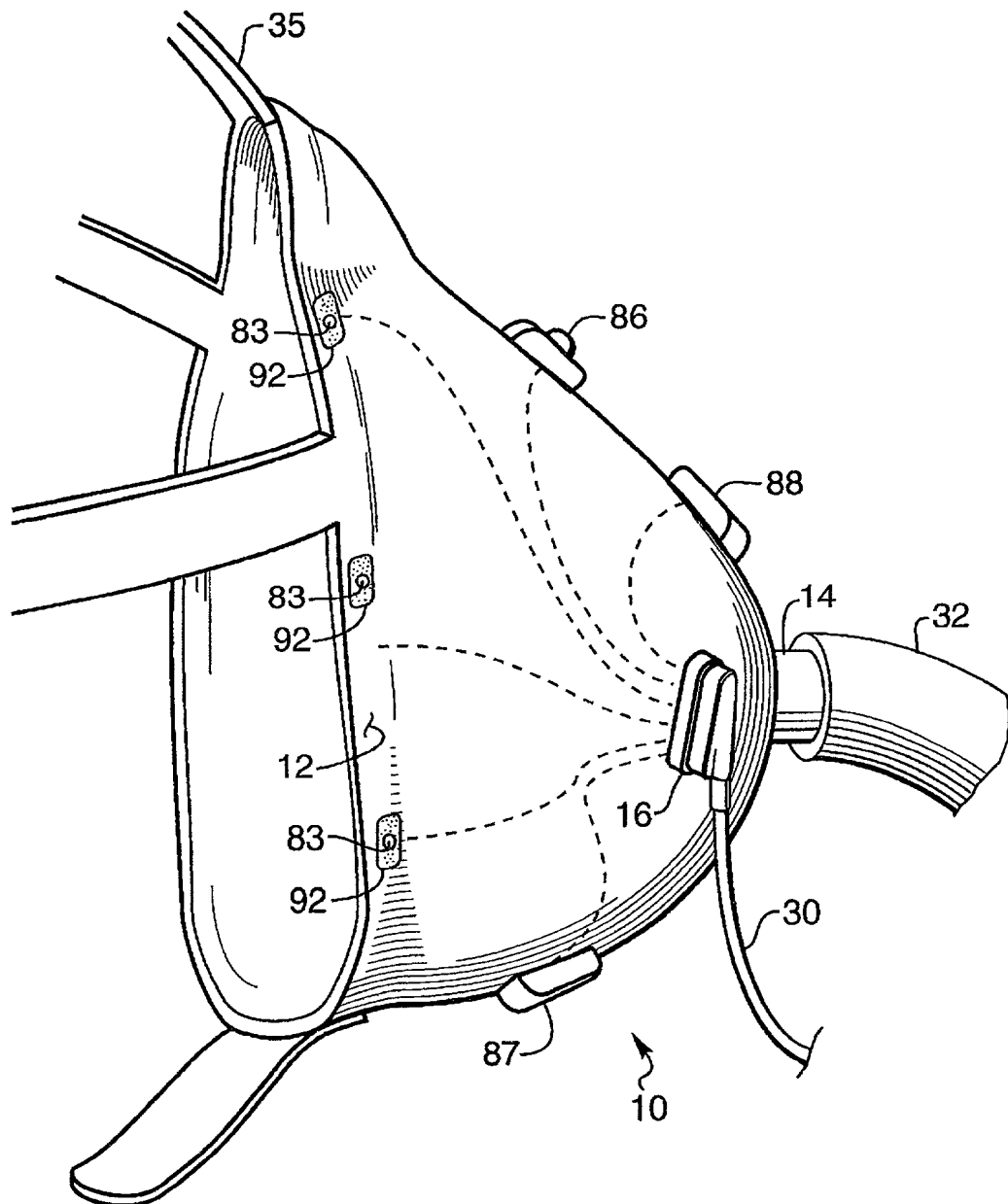*Fig. 6*

4/4

Fig. 7

ATTORNEY FILE NO. 990326.ORI

DECLARATION, POWER OF ATTORNEY, AND PETITION

I, DAVID BURTON, a citizen of the Australia, residing at 62 Camberwell, VIC 3124, Australia, hereby declare that: my residence, post office address and citizenship are as stated above next to my name; and that I verily believe I am the original, first and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled "BIO-MASK", the specification of which is attached hereto.

I hereby state that I have reviewed and understand the contents of the specification including the claims as amended by any amendment specifically referred to in the Oath or Declaration.

I acknowledge the duty to disclose information which is material to patentability in accordance with Title 37, Code of Federal Regulations, Section 1.56.

I hereby appoint NIKOLAI, MERSEREAU & DIETZ, P.A., a professional association, consisting of the following attorneys/agents and the following attorneys/agents individually: Thomas J. Nikolai, Registration No. 19,283, Charles G. Mersereau, Registration No. 26,205, Paul T. Dietz, Registration No. 38,858, and Steven E. Kahm, Registration No. 30,860, of 820 International Centre, 900 Second Avenue South, Minneapolis, Minnesota 55402-3813; Telephone No. (612) 339-7461, my attorneys/agents with full power of substitution and revocation to prosecute this application and transact all business in the Patent and Trademark Office connected herewith.

1

Please direct all telephone calls and correspondence to: Steven E. Kahm, Esq. at NIKOLAI, MERSEREAU & DIETZ, P.A., 820 International Centre, 900 Second Avenue South, Minneapolis, Minnesota 55402-3813.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name: _____
DAVID BURTON

Date: 16/12/99

2